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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/493,480	01/28/2000	Martin A. Cheever	0140580-009810	2303

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EXAMINER

HUNT, JENNIFER ELIZABETH

ART UNIT PAPER NUMBER

1642

DATE MAILED: 05/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/493,480

Applicant(s)
Cheever et al.

Examiner
Jennifer Hunt

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 17, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 93-124 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 93, 97-103, 107-116, 121, and 124 is/are rejected.
- 7) ☒ Claim(s) 94-96, 104-106, 117-120, 122, and 123 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Response to Amendment

1. Acknowledgment is made of applicant's addition of new claims 117-124. Claims 93-124 are pending in the application and considered herein.

Objections/Rejections Withdrawn

2. The objection to the specification for use of the trademark Herceptin has been withdrawn in light of the amendments thereto.

3. The rejection of claim 116 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the use of the trademarks "Q sepharose High Performance Columns", and "Phenyl Sepharose 6 Fast Flow low substitution" is withdrawn in light of the amendments thereto.

4. The rejection of claims 94-96 and 104-106, under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, the written description rejection, is withdrawn in light of the amendments thereto.

5. The rejection of claims 99-102 and 109-112 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide composition

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comprising SEQ ID NO:6 or 7, or a fusion of SEQ ID NO:3 to 4, or 3 to 5 and the corresponding vectors, host cells, and methods of making a polypeptide, does not reasonably provide enablement for the corresponding pharmaceutical composition is withdrawn in light of the amendments thereto.

Claim Rejections Maintained

6. The rejection of claims 93, 97-103, and 107-116 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, the written description rejection, is maintained for reasons of record, and applied to newly added claims 121 and 124.

The previous rejection stated that claims 93-116 are broadly drawn to a polynucleotide of any size comprising a sequence that is at least 80% homologous to SEQ ID NO: 6, or 7, or a fusion of SEQ ID NO:3 to 4, or of 3 to 5 and the corresponding vectors, host cells, and methods of making a polypeptide. Thus claims are drawn to a polynucleotide of any size which is only defined by a small number of nucleic acid residues, hence the claims are drawn to nucleic acid residues which minimally contain only portions of SEQ ID NO:3-7. Accordingly, the claims are drawn to a large genus of molecules. In the case of small identified nucleic acid residues claimed with open language, the genus of the polynucleotides comprising a partial sequence encompasses a variety of subgenera with widely varying attributes. The specification discloses only the

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structural features of the species SEQ ID NO:3-7. The specification lacks information to lead one of ordinary skill in the art to understand that the applicant had possession of the broadly claimed genus of polynucleotides at the time the instant application was filed. Applicant is referred to the guidelines 112, first paragraph, published in the Official gazette and also available on www.uspto.gov.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*.” (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 115).

Applicant argues that the amendments to the claims, which recite that the claimed nucleotide sequences would hybridize under specific conditions to the nucleic acid sequences of the various combinations of SEQ ID NO:’s 2-8, provides written description rejection for the claimed nucleotide sequences because the hybridization language provides a precise functional and structural definition of the claimed invention. Applicant’s arguments filed January 17, 2002 have been fully considered but are not persuasive.

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A sequence which hybridizes to a molecule need only share a small region of homology with the sequence to which it hybridizes. Thus homology over a very small portion of the molecule would still meet the limitations of the claim. And thus the claims still encompass a large genus of molecules (any molecule which shares a small region of homology, regardless of the overall homology of the molecule) and thus the rejection is maintained for the reasons set forth above and in the previous office action.

New Claim Objections

7. Claims 94-96, 104-106, 117-120, and 122-123 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Claims 94-96, 104-106, 117-120, and 122-123 are objected to. Claims 93, 97-103, 107-116, 121, and 124 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Hunt, whose telephone number is (703) 308-7548. The examiner can normally be reached Monday through Thursday 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (703) 308-3995. The fax number for the group is (703) 305-3014 or (703) 308-4242.

Communications via internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [anthony.caputa@uspto.gov].

All internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists the possibility that sensitive information could be identified or exchanged unless the record includes a properly

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signed express waiver of the confidentiality requirements of U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist, whose telephone number is (703) 308-0196.

Jennifer Hunt

May 19, 2002


SHEELA HUFF
PRIMARY EXAMINER